



FDA News



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FOR IMMEDIATE RELEASE  
PO3-04  
January 29, 2003

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## **PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS PROPOSAL**

FDA today announced a proposed regulation that would require that prior notice be given to FDA before food is imported or offered for import into the United States. This proposed regulation is an important milestone in implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This new legislation provided FDA with new authority for protecting the nation's food supply against terrorist acts and other public health threats. The prior notice provision in the Act would give FDA advance information of imported food shipments, which would allow FDA to target inspections more effectively and to help ensure the safety of imported food products before they enter domestic commerce.

Under the proposal, FDA must be notified by noon of the calendar day before the day the imported food will arrive at the U.S. border crossing or at the port of entry. The proposed rule would require the prior notice to be submitted electronically through an FDA Internet-based system that would be operational 24 hours a day, seven days a week.

FDA anticipates that an average of approximately 20,000 prior notices concerning imported food will be submitted daily.

"The more we know about the source of the food we eat the better prepared we'll be to monitor its safety," said Secretary of Health and Human Services Tommy G. Thompson. "We are determined to do everything we can to preserve the American public's confidence in the safety and security of the food supply."

"This is one of a series of critical steps we are taking to strengthen our ability to protect the food supply," said FDA Commissioner, Dr. Mark B. McClellan. "FDA is dedicated to fulfilling its mission as one of the nation's frontline defenses against terrorism. Thanks to the efforts of Senators Gregg and Kennedy, and Representatives Tauzin and Dingell, the Bioterrorism Act gives FDA this important new authority."

The Bioterrorism Act requires that FDA receive prior notice beginning December 12, 2003, even if final regulations have not issued by that date. In the proposed rule, FDA is offering the public 60 days to comment on the proposed rule and states that it plans to issue a final rule by October 12, 2003, after considering the comments it receives.

The proposed rule does not apply to food carried in an individual's personal baggage entering the United States for that person's personal use, or to meat, poultry or egg products that are exclusively regulated by the U.S. Department of Agriculture at the time of importation. All other imported food, including beverages, would be subject to the prior notice requirements, whether or not the food is intended for consumption in the United States.

The proposed rule would require the prior notice to contain the following information for each imported food entry:

- ?? Identification of the submitter, including name and firm information
- ?? Entry type and U.S. Customs System (ACS) entry number, or other U.S. Customs identification number for the import
- ?? The location for any imported food products held at the port of entry for failure to submit an adequate prior notice
- ?? The identification of the articles of food, including complete FDA product code, the common or usual name or market name, the trade or brand name (if different from the common or market name), the quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable)
- ?? The identification of the manufacturer
- ?? The identification of the grower, if known
- ?? The originating country
- ?? The identification of the shipper
- ?? The country from which the article of food was shipped
- ?? The anticipated arrival information: location, date, and time
- ?? U.S. Customs entry process information
- ?? The identification of the importer, owner, and consignee
- ?? The identification of the carrier

The proposed rule would allow product identity information in prior notices to be amended if complete product identity information does not exist by the prior notice deadline.

The Bioterrorism Act states that it is a prohibited act to import or offer for import an article of food without prior notice, and that food imported or offered for import without adequate prior notice will be refused admission and held at the port of entry until adequate prior notice is received, unless FDA directs its removal to a secure facility.

Single copies of the proposed regulation outlined above, which went on display today at the Office of the Federal Register, may be obtained by writing the Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852. This proposal can be accessed electronically at the FDA web page on the Bioterrorism Act: [www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html). FDA will accept comments on Prior Notification of Imported Food Shipments (Docket Number 02N-0278) for 60 days from the date it appeared in the *Federal Register*. Written comments on this proposed regulation can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically through [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments) or through the Bioterrorism Act web page at [www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html). It is important to include the docket number 02N-0278 when providing comments.